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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,875	06/27/2005	Chris Armstrong	ERP01.007APC	6263
20995 7590 10/15/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER HA, JULIE	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 10/15/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/510,875	<b>Applicant(s)</b> ARMSTRONG ET AL.	
	<b>Examiner</b> JULIE HA	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: 10 and 11.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1,3-6,8,9,12-16,24 and 25.  
 Claim(s) withdrawn from consideration: 19-23.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
 Please see continuation of 11 below.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Julie Ha/  
 Examiner, Art Unit 1654

/Anish Gupta/  
 Primary Examiner, Art Unit 1654

The amendments filed raise new 112, first and second paragraph issues that would require further consideration and/or search.

Continuation of 11 below: Claims 1, 3-6, 8-9, 12-16, 24 and 25 remain rejected under 35 U.S.C. 112, first paragraph, as set forth in the previous office action.

Applicant argue that "in order for a polypeptide to function as the protein kinase substrate, the sequence need two requirements, which are a specificity conferring portion and a phosphorylatable portion..." Applicant further argues that "three different polypeptides, each of which comprised a quite different specificity conferring portion (i.e. "RART", "KKLNRT", and "RRR") and a common phosphorylatable portion (i.e. "LSFAEPG") were tested for their phosphorylation by a variety of kinases....the tested polypeptides were efficiently phosphorylated by the kinases to at least a degree comparable to the standard substrate." Applicant argues that "the present application expressly discloses the functional and structural requirements of a polypeptide to the claimed protein kinase substrate."

Applicant's arguments have been considered but have not been found persuasive. As noted in the previous office action, the specification discloses that the preferred consensus sequence is Arg-Arg-Arg-Xaa-Xaa-Ser, Arg/Lys-Xaa-Arg-Xaa-Xaa-Ser, Hyd-Xaa-Arg-Xaa-Xaa-Ser or Xaa-pSer-Xaa-Xaa-Ser, and that a specificity conferring portion comprises an amino acid sequence corresponding to a consensus sequence for a protein kinase, wherein the sequence corresponding to the consensus sequence is positioned relative to the sequence LSFAEPG such that the protein kinase is capable of phosphorylating the polypeptide at the serine residues of the sequence LSFAEPG (see paragraph [0033]). The claims recite that each of the protein kinase substrate polypeptide is of less than 40, 30, 20, 19, 18, 17, 16, 15 or 14 amino acids in lengths. This implies that 39-7 is 32 different amino acid residues for the other 32 residues. For consensus sequence that is Arg-Arg-Arg-Xaa-Xaa-Ser, Arg/Lys-Xaa-Arg-Xaa-Xaa-Ser, Hyd-Xaa-Arg-Xaa-Xaa-Ser or Xaa-pSer-Xaa-Xaa-Ser, there are 2 and 3 undefined positions. This implies that there are  $1.05 \times 10^6$  possibilities for 2 undefined positions, and  $3.49 \times 10^9$  possibilities for 3 undefined positions. There are 20 naturally occurring amino acids. When non-natural amino acids are considered, the numbers are innumerable. Furthermore, the consensus sequences KKLNRT and RRR do not correspond to the consensus sequence that are Arg-Arg-Arg-Xaa-Xaa-Ser, Arg/Lys-Xaa-Arg-Xaa-Xaa-Ser, Hyd-Xaa-Arg-Xaa-Xaa-Ser or Xaa-pSer-Xaa-Xaa-Ser. As described in the previous office action, the specificity conferring portion may overlap with the sequence LSFAEPG. The specificity conferring consensus sequence "RART" corresponds to Arg/Lys-Xaa-Arg-Xaa-Xaa-Ser, wherein the first amino acid is Arg, second is Ala, the third is Arg, the fourth is Thr, the fifth is Leu and the sixth is Ser. The first and the sixth amino acids correspond to the first and the second amino acids of LSFAEPG. However, the other consensus sequences do not correspond, since Arg-Arg-Arg-Xaa-Xaa-Ser does not correspond to KKLNRTLSFAEPG or RRRLSFAEPG. Therefore, the description of RARTLSFAEPG (11mer), KKLNRTLSFAEPG (13mer), or RRRLSFAEPG (10mer) for substrate polypeptide is not sufficient to encompass numerous other substrate polypeptide that belong to the same genus. There are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus, as described previously.